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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,789	07/02/2003	Milan Sojka	30530/38803	5462

4743 7590 04/06/2006

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EXAMINER

HAWES, PILI ASABI

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,789	SOJKA, MILAN	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10-27-2003, 12-28-2004</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 10-27-2003, 12-28-2004 is acknowledged. Claims 1-22 are pending in this action. Claims 1-22 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8,9, 11, 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dansereau et al. US 5622721.

Dansereau teaches controlled release dosage forms comprising an active agent and cellulose fibers (col. 11, lines 1, 43-45, 63). The compressed tablets are coated with enteric coatings that retard the release of the active agent (col. 11, lines 5-10). Cellulose polymers such as ethylcellulose, hydroxycellulose, hydroxypropylmethylcellulose, methylcellulose are taught (col. 12, lines 5-10). The pharmaceutical composition comprises 0.25-40.00% of the active agent and 60-99.75% of the pharmaceutically acceptable excipients (col. 5, lines 60-65). Pharmaceutically acceptable excipients include viscosity agents (col. 8, line 24), and viscosity agents include methylcellulose, carboxymethylcellulose and hydroxypropylmethylcellulose (col. 8, line 57). Risedronate is a water soluble drug.

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Claims 1, 3-5, 10, 12-16, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoeg et al. US 5441732.

Hoeg teaches a topical composition which is a reversibly gelling aqueous and oil emulsion composition comprising a pharmaceutical compound, alkylcellulose, hydroxyalkylcellulose (claims 1 and 2). The pharmaceutical compound is oil soluble (claim 18). The composition has antibacterials such as bacitracin (col. 14, line 30) or antiparasitics such as clindamycin and corticosteroid (col. 14, lines 67). The composition also has silicone oils (col. 9, line 10), used in an amount from 1-20% (col. 9, lines 17-18). The sustained release composition is a solid or semi-solid (col. 1, line 33). The composition is topically applied to the tissues of the eyes.

Claims 1, 6, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Steiner et al. US 4888420.

Steiner teaches making microparticles with cellulose acetate (col. 1, lines 5-10). The particles are used to immobilize enzymes (col. 1, lines 12-13). The cellulose fibers are obtained by esterifying wood pulp or cotton linters (col. 2, lines 16-20). The particles size are 1-1000 microns (col. 2, line 15). The cellulose acetate is used as a carrier for controlled release of active agents, such as those listed in column 4, lines 19-40).

Claims 1, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill et al. US 4233295.

Hill teaches a topical cream or lotion formulation that comprises an active ingredient and carboxymethylcellulose (col. 7, lines 45-55). The compositions are to treat dermatitis by topically administering the compositions (claims 14-16).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615


THURMAN K. PAGE
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TECHNOLOGY CENTER 1600